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10/657,144	09/09/2003	David Alexander	IMMR023/05US	1898

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COOLEY GODWARD LLP
ATTN: PATENT GROUP
11951 FREEDOM DRIVE, SUITE 1700
ONE FREEDOM SQUARE- RESTON TOWN CENTER
RESTON, VA 20190-5061

EXAMINER

SOTOMAYOR, JOHN

ART UNIT	PAPER NUMBER
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3714

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,144

Applicant(s)

ALEXANDER ET AL.

Examiner

John L. Sotomayor

Art Unit

3714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-14, 18-25 and 29-31 is/are rejected.
- 7) ☒ Claim(s) 15-17 and 26-28 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Response to Amendment

1. This case is a Divisional application of parent case 09/237,969. In response to the amendment filed September 9, 2003, claims 1-11 are canceled and claims 12-31 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 3714

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 12-14,18-22,24-25 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younker (US 5,951,301) in view of Bailey (US 5,800,179).

Regarding claim 12, Younker discloses a mock anatomical apparatus having an orifice configured to receive a peripheral device (Fig 1), a resiliency-providing material through which a peripheral device is guided (Col 5, lines 54-58 and 13-22). Younker does not specifically disclose a sensing assembly. However, Bailey teaches an anatomical apparatus used for training with an orifice configured to receive a peripheral device and guide said device through the apparatus to a sensing assembly (Col 4, lines 9-25). Therefore, it would have been obvious to one of ordinary skill in the art to provide a mock anatomical apparatus having an orifice configured to receive a peripheral device and a resiliency-providing material through which a peripheral device is guided as disclosed by Younker with an orifice configured to receive a peripheral device and guide said device through the apparatus to a sensing assembly as taught by Bailey for the purposes of providing force feedback for insuring greater accuracy in the use of the mock anatomical apparatus for training.

Regarding claim 13, Younker discloses a mock anatomical apparatus wherein a resiliency-providing material is foam (Col 4, lines 64-66).

Regarding claim 14, Younker discloses a mock anatomical apparatus having an orifice configured to receive a peripheral device. Younker does not specifically disclose that the mock anatomical site is pivotable. However, Bailey teaches an apparatus and method with a housing, a mock anatomical site with a pivotable orifice for receiving a peripheral (Col 3, lines 45-67, Col

Art Unit: 3714

4, lines 9-14 and figure 1). Therefore, it would have been obvious to one of ordinary skill in the art to provide discloses a mock anatomical apparatus having an orifice configured to receive a peripheral device as disclosed by Younker with a pivotable orifice for receiving a peripheral as taught by Bailey for the purposes of better simulating patient orientation during training procedures.

Regarding claims 18 and 29, Younker discloses a mock anatomical apparatus having an orifice configured to receive a peripheral device, coupled and spaced apart from a housing (Col 5, lines 13-35 and Fig 1). Younker does not specifically disclose a sensing assembly. However, Bailey teaches an anatomical apparatus used for training with an orifice configured to receive a peripheral device and guide said device through the apparatus to a sensing assembly (Col 4, lines 9-25). Therefore, it would have been obvious to one of ordinary skill in the art to provide a mock anatomical apparatus having an orifice configured to receive a peripheral device, coupled and spaced apart from a housing as disclosed by Younker with an anatomical apparatus used for training containing a sensing assembly as taught by Bailey for the purposes of providing force feedback to students using the mock anatomical apparatus for training.

Regarding claims 19 and 30, Younker discloses a mock anatomical apparatus used for training having an orifice configured to receive a peripheral device. Younker does not specifically disclose that the apparatus comprises a mock face and a mock torso housing. However, Bailey teaches a mock anatomical apparatus that comprises a mock face and a mock torso housing (Fig 1). Therefore, it would have been obvious to one of ordinary skill in the art to provide a mock anatomical apparatus used for training having an orifice configured to receive a

Art Unit: 3714

peripheral device as disclosed by Younker with a mock face and a mock torso housing as taught by Bailey for the purposes of greater verisimilitude with a human subject.

Regarding claims 20 and 31, Younker discloses a mock anatomical apparatus used for training in which a mock anatomical site is functionally coupled to a pivotable torsion tube (Fig 3).

Regarding claim 21, Younker discloses a method using a mock anatomical apparatus wherein the apparatus has an orifice configured to receive a peripheral device (Fig 1), and a resiliency-providing material through which a peripheral device is guided (Col 5, lines 54-58 and 13-22). Younker does not specifically disclose that the apparatus is pivotable or lockable into a desired position. However, Bailey teaches an apparatus and method with a housing, a mock anatomical site with a pivotable orifice for receiving a peripheral, in which said orifice may be locked into position (Col 3, lines 45-67, Col 4, lines 9-14 and figure 1). Therefore, it would have been obvious to one of ordinary skill in the art to provide a method for using a mock anatomical apparatus wherein the apparatus has an orifice configured to receive a peripheral device, and a resiliency-providing material through which a peripheral device is guided as disclosed by Younker in which the apparatus is pivotable or lockable into a desired position as taught by Bailey for the purposes of better simulating patient orientation during training procedures.

Regarding claim 22, Younker discloses a method using a mock anatomical apparatus wherein the apparatus comprises a resilient material and has an orifice configured to serve as the point of entry of a peripheral device during a medical training procedure. Younker does not specifically disclose that the site of entry may be pivoted and locked during a training procedure.

Art Unit: 3714

However, However, Bailey teaches an apparatus and method with a housing, a mock anatomical site with a pivotable orifice for receiving a peripheral, in which said orifice may be locked into position (Col 3, lines 45-67, Col 4, lines 9-14 and figure 1). Therefore, it would have been obvious to one of ordinary skill in the art to provide a method using a mock anatomical apparatus wherein the apparatus comprises a resilient material and has an orifice configured to serve as the point of entry of a peripheral device during a medical training procedure as disclosed by Younker in which a pivotable orifice for receiving a peripheral may be locked into position as taught by Bailey for the purposes of securing the entry site during training to provide better feedback data during the training procedure.

Regarding claim 24, Younker discloses a mock anatomical apparatus having an orifice configured to receive a peripheral device (Fig 1), a resiliency-providing material through which a peripheral device is guided (Col 5, lines 54-58 and 13-22). Younker does not specifically disclose a sensing assembly or that the mock anatomical site is pivotable. However, Bailey teaches an anatomical apparatus used for training with an orifice configured to receive a peripheral device and guide said device through the apparatus to a sensing assembly (Col 4, lines 9-25) a mock anatomical site with a pivotable orifice for receiving a peripheral, in which said orifice may be locked into position (Col 3, lines 45-67, Col 4, lines 9-14 and figure 1). Therefore, it would have been obvious to one of ordinary skill in the art to provide a mock anatomical apparatus having an orifice configured to receive a peripheral device and a resiliency-providing material through which a peripheral device is guided as disclosed by Younker with an pivotable orifice configured to receive a peripheral device and guide said device through the

Art Unit: 3714

apparatus to a sensing assembly as taught by Bailey for the purposes of providing force feedback for insuring greater accuracy in the use of the mock anatomical apparatus for training.

Regarding claim 25, Younker discloses a mock anatomical apparatus wherein a resiliency-providing material is foam (Col 4, lines 64-66).

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Younker (US 5,951,301) in view of Bailey (US 5,800,179) in further view of Blaine (US 4,439,162).

Younker/Bailey does not specifically disclose a mock training apparatus and method in which the mock anatomical site includes pivoting the mock anatomical site to simulate an individual lying on their side and a position simulating an individual lying on their back. However, Blaine teaches a mock anatomical training device in which the device may be pivoted such that a plurality of mock anatomical sites located on the training device simulate an individual lying on their back or on their side (Fig 1 and Col 6, lines 23-42). Therefore, it would have been obvious to one of ordinary skill in the art to provide a mock anatomical apparatus and method wherein the apparatus comprises a resilient material and has an orifice configured to serve as the point of entry of a peripheral device during a medical training procedure as disclosed by Younker/Bailey in which the apparatus includes pivoting the mock anatomical site to simulate an individual lying on their side and a position simulating an individual lying on their back as taught by Blaine for the purposes of providing a greater array of training positions for each user.

Allowable Subject Matter

Claims 15-17 and 26-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the

Art Unit: 3714

base claim and any intervening claims. The claims recite the limitations of the pivotable mock anatomical site consisting of a retainer and ring proximate to the orifice configured to rotate and lock the orifice into position and using one of a frictional force and a pressure force to prevent movement of the orifice.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John L Sotomayor whose telephone number is 703-305-4558. The examiner can normally be reached on 6:30-4:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 703-308-1806. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jls
May 14, 2004



JESSICA HARRISON
PRIMARY EXAMINER